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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,421	09/26/2000	Dale Wallis	40224.00001	5703

7590 05/30/2003

Squire Sanders & Demsey LLp
801 S Figueroa St 14th Fl
Los Angeles, CA 90017-5554

EXAMINER
NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
1645	16

DATE MAILED: 05/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/670,421	Wallis et al
Examiner	**Art Unit**
Mark Navarro	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *12-26* is/are pending in the application.

4a) Of the above, claim(s) *12-17 and 19* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *18 and 20-26* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

REQUEST FOR CONTINUED EXAMINATION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Additionally, Applicant's amendment filed May 1, 2003 has been received and entered. New claims 20-26 have been added, consequently claims 12-26 are pending in the instant application, of which claims 12-17 and 19 have been withdrawn from further consideration as being drawn to a non-elected invention in Paper Number 6, received January 22, 2002.

Claim Rejections - 35 USC § 112

1. The rejection of claim 18 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition of Serpens strain HBL-112, does not reasonably provide enablement for all pharmaceutical compositions of Serpens, immunologically active portions thereof, and antigenic epitopes cross-reactive with the Serpens genera is maintained. Additionally this rejection is applied to newly added claims 20-26.

Applicant's are asserting that using a well known technique called epitope mapping, a person skilled in the art can identify and locate "immunogenically active portions" of bacterial

species belonging to the genus Serpens and "an antigenic epitope that is cross-reactive with an antibody that immunologically reacts with the bacterial species." Applicants further assert that by claiming "immunogenic compositions" the newly added claims obviate the requirement of demonstrating a protective response has been elicited.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants specification demonstrates that compositions of Serpens strain HBL-112 when administered to dairy cows resulted in reduced lesion size and duration. However, this is simply not commensurate in scope with "immunologically active portions or cross reactive epitopes. Strain HBL-112 displays a multitude of surface antigens. Applicants claim encompasses fragments from any single one of these antigens. This point has been emphasized by Ellis, R.W. (see Chapter 29 of "VACCINES" [Plotkin, S.A *et al.*,(ed.), published by W.B. Saunders Company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] which exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies ...and thus protect the host against attack by the pathogen." In other words Applicants have shown protection with an attenuated microorganism (HBL-112) but now attempt to claim protection with any single fragment of any single protein. Which of the many proteins displayed on Serpens is responsible for this protection? Applicants specification is completely silent as to which protein one of skill in the art would use effectively.

Given that the art teaches single antigens to be unpredictable, one of skill in the art would clearly be forced into undue experimentation to practice the claimed invention.

Second, Applicants assert that it is routine to identify "immunogenically active portions" of bacterial species. While this statement is agreed upon, it is not germane to the rejection. Any sequence of amino acids under the right conditions can elicit or react with an antibody. However, it does not follow that the resulting immune response will be one of protection. A vaccine "must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." In re Wright, 999 F.2d 1557,1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Finally, Applicants state that the newly added claims recite "immunogenic compositions" and therefore obviate the requirement of demonstrating protective immunity. However, Applicants are respectfully directed to their own claim language. Newly added claims 20-26 each recite "an immunogenic composition for the **prevention and treatment** of Papillomatous Digital Dermatits." (Emphasis added). The requirement of demonstrating protective immunity is therefore still present.

The claims are directed to pharmaceutical compositions for the prevention and treatment of Papillomatous Digital Dermatitis in ruminants comprising a therapeutically effective amount of at least one member selected from the group consisting of bacterial species belonging to the genus

Serpens; an immunologically active portion thereof; and an antigenic epitope cross-reactive with the Serpens genera in combination with a veterinarily acceptable diluent or a carrier.

It is well recognized in the art that it is unclear whether a single protein derived from a pathogen will elicit protective immunity. Ellis, R.W. (see Chapter 29 of "VACCINES" [Plotkin, S.A *et al.*,(ed.), published by W.B. Saunders Company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies ...and thus protect the host against attack by the pathogen." Fox (U.S. Patent Number 4,879,213) sets forth that "without knowing a protein's three dimensional structure there is no reliable method for determining which linear segments of the protein are accessible to the host's immune system" and that "whether the three dimensional structure is known or not, short linear polypeptides often appear not to have the ability to mimic the required secondary and tertiary conformational structures to constitute appropriate immunogenic and antigenic determinants." Consequently determining immunologically active portions or antigenic epitopes cross-reactive with the Serpens genera is unpredictable and would require undue experimentation as evidenced by Plotkin *et al* and Fox *et al.*

For reasons of record in Paper Number 11, as well as the reasons set forth above, this rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The rejection of claim 18 under 35 U.S.C. 102(b) as being anticipated by Hespell is maintained. Additionally this rejection is applied to newly added claims 20 and 24.

Applicants are asserting that Hespell does not teach or suggest the attenuated form of species belonging to the Serpens genera. Applicants further assert that Hespell does not teach of suggest any other species belonging to the genus Serpens. Applicants finally assert that the new claims also recite a negative VP test, and do not reduce nitrite to nitrogen, which are distinguishable from Serpens flexibilis.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that Hespell does not teach or suggest the attenuated form of species belonging to the Serpens genera. However, Applicants are respectfully directed to the claim language, none of the rejected claims recite that the Serpens must be attenuated.

Second, Applicants assert that Hespell does not teach of suggest any other species belonging to the genus Serpens. However, Applicants are again respectfully directed to the claims, the only requirement is "a bacterial species belonging to the genus Serpens, or an

immunogenically active portion thereof..." No other species belonging to the genus Serpens is therefore required.

Finally, Applicants assert that the new claims also recite a negative VP test, and do not reduce nitrite to nitrogen, which are distinguishable from Serpens flexibilis. However, claims reciting these limiations have not been rejected.

The claims are directed to pharmaceutical compositions for the prevention and treatment of Papillomatous Digital Dermatitis in ruminants comprising a therapeutically effective amount of at least one member selected from the group consisting of bacterial species belonging to the genus Serpens; an immunologically active portion thereof; and an antigenic epitope cross-reactive with the Serpens genera in combination with a veterinarily acceptable diluent or a carrier.

Hespell (International Journal of Systematic Bacteriology, Vol. 27, No. 4, pp 371-381, October 1977) disclose of isolated *Serpens flexibilis*. Hespell further discloses of culturing *Serpens flexibilis* in a lactate broth which contains 100 ml of distilled water.

In view that Hespell discloses of an isolated *Serpens flexibilis* in combination with a veterinarally acceptable diluent (distilled water), the disclosure of Hespell is seen to anticipate the claimed invention.

It is noted that Hespell does not set forth that the composition is used for the prevention and treatment of Papillomatous Digital Dermatitis in ruminants, however such a recitation is an intended use of the claimed composition, and therefore, carries no weight when compared to the disclosure of Hespell.

For reasons of record in Paper Number 11, as well as the reasons set forth above, this rejection is maintained.

Double Patenting

3. The rejection of claim 18 under the judicially created doctrine of obviousness-type-double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,162,429 is withdrawn in view of Applicants filing of a terminal disclaimer, which has been recorded.

The following new grounds of rejection are applied to the claims:

Claim Rejections - 35 USC § 112

4. Claims 21-23 and 25-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 21-23 and 25-26 recite that the bacterial species do not produce acetoin from pyruvate, do not reduce nitrite to nitrogen and is attenuated. However, while the specification sets forth that Serpens HBL-112 does not produce acetoin from pyruvate and does not reduce

nitrite to nitrogen (pages 11 and 13), it is not supportive of claiming **any** Serpens bacterial species with these properties. As to the newly filed limitation of being attenuated, the word is never mentioned within the specification as filed. Again, while Applicants refer to a HBL-112 bacterin, this is not commensurate in scope with any attenuated Serpens strain. Furthermore, while bacterins are usually killed microorganisms, an attenuated microorganism can just as easily be created by deletion of virulent genes. Consequently, the term attenuated is also deemed new matter.

Accordingly, Applicant is required to demonstrate clear support for the newly filed claims or cancel the newly added material.

5. Claims 18 and 20-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 18, and 20-26 recite a composition for the prevention and treatment of Papillomatous Digital Dermatitis in ruminants comprising a therapeutically effective amount of at least one member selected from the group consisting of bacterial species belonging to the genus Serpens, an **immunologically active portion thereof, and an antigenic epitope** in sufficient variety and quantity for protection against Papillomatous Digital Dermatitis that is cross-reactive

with an antibody that immunologically reacts with the Serpens genera in combination with a veterinarily acceptable diluent or a carrier.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a Serpens HBL 112 strain alone is insufficient to describe the genus. Thus, Applicant's have not described a function which is shared by "immunologically active portions or cross reactive epitopes" which would adequately describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should by faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Mark Navarro

Primary Examiner

May 28, 2003